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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,052	08/04/2005	Philippe Chenevier	1017753-000205	5521

21839 7590 03/20/2009
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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03/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/530,052	Applicant(s) CHENEVIER ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/8/09</u> . | 6) <input checked="" type="checkbox"/> Other: <u>FR 2793688A1</u> . |

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DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 1/08/09 was filed after the mailing date of the last Office Action on 10/08/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Chen et al (USPN 6,544,556 hereafter '556) in view of Criere (FR 2,793,688 hereafter '688). The claims are drawn to a pharmaceutical formulation comprising a spheroid core with an enteric coating directly applied and an over coating applied to the enteric coating. The enteric coating comprises a mixture of enteric polymers and surfactants.

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The '556 patent teaches a pharmaceutical formulation comprising a spheroid core wherein the core comprises an active agent such as an NSAID and a proton pump inhibitor such as omeprazole (col. 5, lin. 35-col. 7, lin. 15). The spheroid core has an enteric coating directly applied to it (col. 4, lin. 4-15), where the coating comprises enteric polymers such as hydroxypropylcellulose phthalate, shellac and methacrylic acids along with plasticizers such as polyethylene glycol, along with surfactants like polysorbates (col. 10, lin. 10-25). The core comprises binders such as polyvinylpyrrolidone starches and sugars (col. 8, lin. 60-68). The core further comprises lubricants, and diluents (col. 9, lin. 15-30). The enteric coated spheroids are further coated with an outer coating comprises water soluble polymers such as sugars, polyvinylpyrrolidone and carboxymethylcellulose (col. 10, lin. 30-40). The spheroids are prepared by first making the core and then applying the successive coating compositions in a fluidized bed device (col. 14, lin. 9-16). Although the reference discloses an enteric coating formulation mixed with other coating polymers they are silent to the specific components of the instant claims. The specific combination is described in the '688 patent.

The '688 patent discloses a control release formulation comprising granules coated with a mixture of an enteric polymer and a fatty acid (abstract). The granules are coated with a mixture comprising Eudragit polymers and Gelucire polymers (having a majority of palmitostearic acid having a melting point from 46-51 degrees Celsius and an HLB of 13 (page 12, lin. 20-26). It would have been obvious to coat the core particles of the '556 patent with the coatings of the '688 in order to provide more precise gastrointestinal delivery.

Regarding the direct compressible limitation, it is the position of the Examiner that such a limitation is merely a future intended use limitation. The proposed combination provides a

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structurally complete composition comprising a core, direct coating and a successive water dispersible coating. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

With these aspects in mind it would have been obvious to include the polymers of the '688 patent into the coating compositions of the '556 patent in order to improve the absorption of the active agents being coated. One of ordinary skill in the art would have been motivated to do so since both patents teach that these coating polymers can be applied directly to the drug containing core and discloses similar coating compositions. It would have been obvious to combine the teachings and suggestions as such with an expected result of stable core formulation useful in direct tableting with improved drug absorption properties.

Response to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection. The Chen patent however discloses a core material directly coated with an enteric polymer coating and a further water dispersible coating. Applicant argues that directly compressible spheroids are not disclosed, however seeds are disclosed where the seeds are coated and compressed to form a tablet. The cores are not disclosed as spheroids explicitly, yet the components are identical and would have been obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

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0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618